

STATEMENT OF :

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**BEFORE THE HOUSE COMMITTEE ON HOMELAND SECURITY
SUBCOMMITTEE ON EMERGENCY PREPAREDNESS, SCIENCE AND TECHNOLOGY**

**"PROJECT BIOSHIELD: LINKING BIOTERRORISM THREATS AND
COUNTERMEASURE PROCUREMENT TO ENHANCE TERRORISM PREPAREDNESS."**

TUESDAY, 12 JULY

Chairman King, Congressman Pascrell, members of the committee, thank you for the opportunity to appear before you on this critically important subject of Project BioShield and chemical, biological, radiological, and nuclear medical countermeasures. My name is Nancy Wysenski and I am the President of EMD Pharmaceuticals, located in Durham, North Carolina. EMD is a research and technology company specializing in the areas of neurodegenerative diseases, oncology and cardio metabolic care. Our parent company is also the global provider of *Cyanokit*, a cyanide antidote kit designed specifically to be used as an immediate field antidote against large scale cyanide poisoning whether resulting from chemical terrorism, industrial accidents, or due to smoke inhalation. This promising technology has the potential to provide dual use protection – it has potential benefits not only for responding to terrorist incidents, but also, to everyday emergencies where first responders and others fall victim to smoke-inhalation every day. EMD's Cyanokit is precisely the type of countermeasure the government should be considering for broad deployment to both the Strategic National Stockpile and first responders throughout the country.

EMD, a subsidiary of Merck, KGaA, is currently working with the Food and Drug Administration to register this product in the United States. Indeed, the FDA's Division of Counter-Terrorism has shown significant interest in our development plan to obtain US marketing approval. Clinical trials are in progress for the use of *hydroxocobalamin*, the chemical name for the compound comprising Cyanokit, in countering what we believe should be one of the most concerning chemical threats facing Homeland Security: cyanide poisoning.

The Threat:

Mr. Chairman, cyanide is one of the most prevalent industrial chemicals in use today in the United States. It is also one of the most deadly chemicals in the environment. Nearly 100,000 tons are produced by various industries in the United States annually, with most of it shipped via our inter-modal transportation system; including rail, highway and waterway transportation systems. Cyanide also remains one of the deadliest – and most widely available potential agents for use by terrorists as identified by U.S. intelligence sources.

In public documents released by the Central Intelligence Agency (CIA) on the potential threat of Chemical, Biological, Radiological and Nuclear attacks (CBRN) to the U.S., cyanide is listed as the leading potential chemical agent of choice by terrorist groups. The relative ease of access and plentiful supply make cyanide a particularly attractive method for inflicting large scale harm to the general population. Specifically, the CIA cites the following rationale as to why much greater concern should be given regarding the potential use of cyanide by terrorist groups:

*“Several groups of Mujahidin associated with al-Qa’ida have attempted to carry out “poison plot” attacks in Europe with easily produced chemicals and toxins best suited to assassination and small-scale scenarios. These agents could cause hundreds of casualties and widespread panic if used in multiple simultaneous attacks... Exposure to cyanide may produce nausea, vomiting, palpitations, confusion, hyperventilation, anxiety, and vertigo that may progress to agitation, stupor, coma, and death. At high doses, cyanides cause immediate collapse.”*¹

The most important point to be drawn from the CIA’s analysis is the need to have immediate and adequate quantities of antidotes made available in the field prior to the emergency or attack to provide the greatest chance of survival.

However, the reality of the current state of preparedness for meeting the threat of cyanide poisoning is disheartening. In 2001, medical experts viewed the ability of the United States to respond to a terrorist incident involving cyanide with a high degree of angst:

*“The United States is under the constant threat of a mass casualty cyanide disaster from industrial accidents, hazardous material transportation incidents, and deliberated terrorists attacks. The current readiness for cyanide disaster by the emergency medical system in the United States is abysmal. We, as a nation, are simply not prepared for a significant cyanide-related event.”*²

This comment came from a publication prior to 9/11, and unfortunately, in the last four years, nothing has changed.

With the passage of Project BioShield, the Department of Homeland Security in conjunction with the Department of Health and Human Services now has the mechanism at hand that can greatly increase U.S. emergency medical preparedness for a cyanide disaster. They will not meet that goal, however, without increased involvement by industry and a demonstrated willingness for the government to push forward with the implementation of Project BioShield in the way Congress intended.

The Challenge:

¹ CIA, “Terrorist CBRN: Materials and Effects”. September 2003.

² Sauer SW, Kein ME. *Hydroxocobalamin: improved public health readiness for cyanide disasters*. Annals of Emergency Medicine. June 2001; 37:635-641

During the legislative process that led to the passage of Project BioShield, both the House Committees on Government Reform, and Energy and Commerce directed that provisions should be made to address the threat of cyanide poisoning under the supervision of the Department of Homeland Security:

*“... under the authority provided by the bill, the government could procure countermeasures against chemical agents (nerve, blister, blood, and pulmonary agents) and radiological and nuclear agents. The Administration currently does not plan to use the bill’s authority to purchase agents that could mitigate threats from these sources, but it could do so if the perceived threat from these agents changed or if certain treatments became scientifically feasible. Countermeasures that could be acquired under Project BioShield include existing treatments for many nerve gases (including VX, Sarin, and Soman gas), Prussian Blue (a treatment for certain types of radiation poisoning), **and hydroxocobalamin (a treatment for cyanide poisoning that is in an advanced stage of development).**”*

EMD did nothing to lobby for this report language. In fact, it was only brought to our attention by our outside counsel in 2004 when we stepped up our efforts for greater outreach to policymakers in Washington D.C. Thus, it appears that the Federal Government – not industry – made Congress aware of the potential benefits of hydroxocobalamin to treat cyanide and the need to purchase this important countermeasure under Project BioShield.

Hydroxocobalamin is being developed as an antidote for treatment of cyanide poisoning due to smoke inhalation, chemical terrorism, or industrial exposure. As previously stated, the product is already registered by EMD’s French affiliate, Merck Sante as a cyanide antidote under the international brand name *Cyanokit*, and currently is stocked on fire trucks and ambulances for first responder use in France where it has been in use for over 8 years.

Once approved for use in the U.S., or even prior to final FDA approval under IND status or Emergency Use Authorization provisions afforded by Project BioShield, hydroxocobalamin can be stockpiled and then administered on-site, at the scene of a chemical terrorism disaster, providing immediate aide to victims. The only currently licensed cyanide kit generally requires transport to a local hospital and, further, is cumbersome to administer, consisting of not just one component but three. More importantly, the current antidote cannot be used for victims for smoke inhalation, because it may actually worsen their medical condition. However, before hydroxocobalamin or Cyanokit is available for use in this manner, and according to the current implementation of Project BioShield by the Departments of Homeland Security and Health and Human Services (DHS and HHS, respectively), DHS must determine that cyanide is a material threat by conducting a Material Threat Assessment (MTA). Even though during the first

days in Afghanistan in 2001, our military seized videotapes from terrorist training camps showing *al-Qa'ida* experimenting with cyanide by poisoning dogs, it is our understanding that, as of yet, no MTA is underway or planned.

Within DHS, the Directorates for Information Analysis and Infrastructure Protection (IAIP) and Science & Technology (S&T) work together in conducting assessments and determinations of biological, chemical, radiological and nuclear agents of greatest concern so as to guide near-term BioShield requirements and acquisitions. Plausible high consequence scenarios that provide an indication of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects are drafted. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process.

To date, the Secretary of DHS has issued Material Threat Determinations for four agents: anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. DHS tells us that additional threat assessments are underway for the remaining Category A biological agents as identified by the Centers for Disease Control and Prevention (plague, tularemia, viral hemorrhagic fevers) and for nerve agents. In our quest for answers, EMD became aware that an MTA had not been conducted for analyzing the cyanide threat and therefore HHS had no grounds for dictating the need for a medical countermeasure against cyanide. Disconcertingly, there appeared to be confusion among the DHS staff as to who would actually conduct the MTA. It is surprising that, to our knowledge, DHS has not addressed the threat of toxic industrial chemicals, such as cyanide, considering the high level recognition of the threat posed by such chemicals.

EMD's status in the BioShield procurement process has been stalled in the very first phase of the Material Threat Determination. For over a year EMD has been seeking answers to questions that clearly have an impact on critical business decisions. Without the MTA from DHS, HHS understandably is not armed with the information necessary to address our questions. We have no indication if the government will buy Cyanokit, when it will buy it, or how much it will buy. Without the MTA, we don't even know if Cyanokit will fit the operational profile of the countermeasure that is called for to meet cyanide countermeasure needs or if it could be adapted to meet those needs. Without such answers, answers that will be informed by the results of an MTA on cyanide, EMD cannot adequately plan for production and facility expansion, and makes us question whether to proceed with product development at our company's expense in making Cyanokit available to the USG. Without a change in that status, the country is not likely to receive the benefit of protection against this looming threat.

The need is clear that more must be done to address the threat of a terrorist created cyanide poisoning event. The international community is acutely aware of just how quickly terrorist organizations are recognizing cyanide poisoning as a leading method for inflicting mass casualties. Without adequate countermeasures in place, on the ground, stockpiled for use in time of emergency, most if not all victims will succumb to the effects of cyanide poisoning. However, without greater cooperation between industry and the government and, most importantly, greater transparency from the Federal government on how Project BioShield is being implemented, companies with the resources and capabilities of EMD will simply not be able to sustain viable interest in this market. The nation, and in fact, the world, cannot afford this risk.

Indeed, the governments of both France and Italy have not only recognized the substantial risks of this threat, but have recently stockpiled significant quantities of Cyanokit to be better prepared in responding to this threat.

In conclusion, I would suggest that given the most recent and graphic terrorist attacks that have been perpetrated in Europe, it is even more important to assess whether we are adequately prepared to deal with the additional threat of a lethal release of cyanide in such a circumstance. The events in Tokyo in 1990's starkly bear this fact out.

If we are to address the threat of cyanide poisoning in the United States, we must move forward with the implementation of Project BioShield as Congress and the President intended. First and foremost, Material Threat Assessments should be completed on all perceived threats. Furthermore, industry needs increased transparency of the BioShield process and feedback from the government to keep us engaged in bio-chem defense efforts and be able to provide the government and public with urgently needed medicines. Enhanced communication and teamwork between DHS and HHS and industry will greatly aid EMD and other companies to bring products from R&D to market for the purpose of defending our Nation against chemical, biological, radiological, and nuclear attacks.

I thank you for your time and I would welcome your questions.